



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,356	08/21/2001	Dale E. Koop	CTC-401	7685
34284	7590	06/07/2004	EXAMINER	
ROBERT D. FISH; RUTAN & TUCKER, LLP P.O. BOX 1950 611 ANTON BLVD., 14TH FLOOR COSTA MESA, CA 92628-1950			FARAH, AHMED M	
			ART UNIT	PAPER NUMBER
			3739	19

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/934,356

Applicant(s)

KOOP, DALE E.

Examiner

Ahmed M Farah

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3, 6, and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Donnell, Jr. U.S. Patent 6,106,514 in view of Purchio et al. U.S. Patent 5,599,788.

O'Donnell, Jr. discloses apparatus and method for treating subsurface layer of skin, the method comprising the steps of:

applying anti-inflammatory, anti-oxidant (wound healing) pharmaceutical agent to the skin (Col. 3, lines 21-26); and

irradiating the skin with laser energy sufficient to cause stimulation of collagen remodeling for the purpose of effecting the tightening of the skin and reducing wrinkles without significantly altering the epidermis (see claims 1-3).

As to claim 3, O'Donnell, Jr. applies mechanical energy to the skin tissue (Col. 6, lines 6-10).

As to claim 8, his treatment reduces wrinkles. Therefore, since wrinkles result from photodamaged and/or aging skin, he provides the claimed method step.

Although O'Donnell, Jr., described above, discloses pharmaceutical agent to enhance the treatment, he does not teach the use of growth factor such as H3 protein to promote the healing process.

However, Purchio et al. disclose a method of producing recombinant transforming growth factor -induced H3 protein and its use to accelerate wound healing **(see Col. 4, line 65 to Col. 5, line 9)**. They further teach that H3 protein may be combined with conventional chemotherapy and radiation treatment to increase the over all treatment efficiency (Col. 4, lines 58--60).

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify O'Donnell, Jr. and apply a growth factor such as H3 protein to the skin as taught by Purchio et al. in order to accelerate the wound healing and to enhance the over all treatment efficiency.

As to claim 6 of the instant application, claim 3 of O'Donnell, Jr. teaches the claimed limitation.

2. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tankovich et al. U.S. Patent 5,817,089 in view of Purchio et al. ('788).

Tankovich et al. disclose phototherapy treatment methods for the reduction and removal of unwanted hair and the mitigation of skin conditions such as acne and seborrhea. However, they do not apply wound healing promoter composition to the skin to enhance the healing process.

Purchio et al., described above, teach the use of a wound healing protein, which may be combined with conventional chemotherapy and radiation treatment to increase

the over all treatment efficiency. Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify the invention of Tankovich et al. with Purchio et al. to apply a wound healing protein to the skin being treated so as to enhance the wound healing process and improve the over all treatment efficiency.

3. Claims 1-3, 6 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Donnell, Jr. U.S. Patent 6,106,514 in view of Hale et al. U.S. Patent 5,607,691.

O'Donnell, Jr. discloses apparatus and method for treating subsurface layer of skin, the method comprising the steps of:

applying anti-inflammatory, anti-oxidant (wound healing) pharmaceutical agent to the skin (Col. 3, lines 21-26); and

irradiating the skin with laser energy sufficient to cause stimulation of collagen remodeling for the purpose of effecting the tightening of the skin and reducing wrinkles without significantly altering the epidermis (see claims 1-3).

As to claim 3, O'Donnell, Jr. applies mechanical energy to the skin tissue (Col. 6, lines 6-10).

As to claim 8, his treatment reduces wrinkles. Therefore, since wrinkles result from photodamaged and/or aging skin, he provides the claimed method step.

Although O'Donnell, Jr., described above, discloses pharmaceutical agent to enhance the treatment, he does not teach the use of growth factor such as H3 protein to promote the healing process.

Hale et al. disclose a method for treating the skin of a patient, the method comprising the steps of: delivering to the skin a pharmaceutical agent such as H3 protein (Col. 26, lines 22-39; Col. 45, lines 35-41; and Col. 51, lines 17-40); and applying EM energy to the skin being treated (Col. 50, lines 27-39).

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify O'Donnell, Jr. and apply a growth factor such as H3 protein to the skin as taught by Hale et al. in order to accelerate the wound healing and to enhance the over all treatment efficiency.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M Farah whose telephone number is (703) 305-5787. The examiner can normally be reached on Mon-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M DVorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

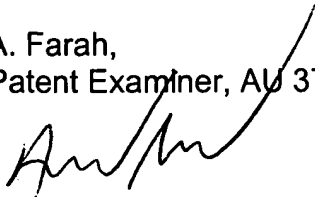
Application/Control Number: 09/934,356

Page 6

Art Unit: 3739

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Farah,
Patent Examiner, AU 3739

A handwritten signature in black ink, appearing to read 'A. Farah', written over the printed name.

05/25/2004.